DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 2 | 2000

1815 '00 AUG 10 A10:10

David Watton, Vice President
Pascal Company, Inc.
P.O. Box 1478
Bellevue, Washington 98009-1478

Dear Mr. Watton:

This letter is in response to your letter addressed to me dated June 20, 2000. In your letter you ask if your company may have permission to continue to sell your oral inhalant drug product, Breatheasy, to long-time customers.

On May 26, 2000, FDA published a final rule requiring that all prescription and over-the-counter aqueous-based drug products for oral inhalation be manufactured sterile (65 FR 34082). The effective date for this rule is May 27, 2002. In your letter, you state that your company does not intend to buy the equipment to manufacture your product to be sterile, and that you plan to discontinue selling the product as of April 30, 2002.

Your letter states that you are concerned about your elderly clientele, many of whom have been using Breatheasy for 40 to 60 years and are convinced no other product will provide them relief from their asthma.

FDA received 49 comments from consumers of Breatheasy and one comment from Pascal Co., Inc., sent to the docket for this rule. As a result of concerns raised by consumers of this product, FDA contacted your company and reviewed the labeling of Breatheasy to determine if it was the type of product intended to be covered by the rule. As you know, Breatheasy is a 2-percent buffered aqueous solution of epinephrine that comes in a kit that contains an atomizer. A determination was made by experts at the agency that Breatheasy is the type of product intended to be covered by the final rule.

In its review of Breatheasy, FDA also determined that other, alternative OTC epinephrine inhalation drug products are on the market available to treat the symptoms of those people who may lose their access to the Breatheasy product. These alternative products do not raise the same safety concerns of microbial contamination raised by Breatheasy. With an effective date two years from the publication of the rule, FDA believes it has given ample time for individuals who may need to find an alternative inhalation product to contact their health care practitioner to assist them in identifying a safe and effective alternative.

FDA's mandate is to protect the public health and safety. FDA believes the final rule requiring the sterile manufacture of aqueous-based drug products for oral inhalation achieves this mandate.

96N-0048

LET 2 / ANS.

Microbial contamination of such products has resulted in severe health consequences and death. The Agency cannot grant an exception for you to continue selling your product to your client base beyond the effective date of the rule.

Sincerely,

Peter Cooney, Ph.D.
Center for Drug Evaluation and Research